ENGLISH Version

Ellipse Light

Operator's Manual

CLINICALLY PROVEN

SAFE AND EFFECTIVE

Ellipse Light Operator's Manual

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Chapter 1: ABOUT THIS MANUAL

1.1 The Manual

The Operator's Manual is designed to provide you with the information needed to use the Ellipse Light System (referred to below as Ellipse Light) safely and effectively. The Manual is divided into five sections:

Section 1 explains the intended use of Ellipse Light, gives background information, and outlines contraindications.

Section 2 explains the day-to-day operation of Ellipse Light including Treatment Scenarios.

Section 3 covers System Maintenance and Hygiene.

Section 4 covers System Safety.

Section 5 supplies Technical Specifications of the System and Applicators.

Throughout the document, cross-references to other sections of the Operator's Manual will be shown in the form "see Section X.Y - Section Name". References to other documentation produced by Danish Dermatologic Development for the Ellipse Light will be in bold text in the form (**Clinical Work Book**). The instruction to press a specific button will be given as in the example "press <Exit>".

Note Ellipse Light uses a touch-sensitive screen instead of a keyboard. To press a button, simply press the screen where the button is located.
This manual offers a brief hands-on guide to use. A more detailed explanation of Ellipse Light will be found in **Operator's Reference Manual** or **Clinical Workbook**.

The Operator's Manual will use the international symbols ⚠CAUTION or ⚠WARNING to denote a possible safety risk if instructions are not carried out correctly.

⚠CAUTION Caution is used to identify conditions or actions for which a potential hazard may exist which will or can cause minor personal injury or property damage if the instructions are ignored.

⚠WARNING Warning is used to identify conditions or actions for where a known hazard may cause severe personal injury, death or substantial property damages if the instructions are ignored.

In order to reduce the likelihood of injury or equipment damage, it is important to read the manual and specifically Section 4 Safety before using the equipment. Always keep the manual nearby, and review the procedures and safety precautions periodically. Contact your DDD representative if you have any questions or feel that additional training is required.

⚠CAUTION Ellipse Light is a Class IIb Medical Device. Do NOT attempt to install or run any software not provided by DDD on the built-in computer system. This may adversely affect safety and reliability.

1.2 Intended Use

The intended uses of Ellipse Light are for medical treatment of changes in the anatomy or of a physiological process in the skin

- Hair removal (permanent hair reduction)
- Treatment of sun-damaged skin to reduce diffuse redness and pigment disturbances and improve texture (Skin Rejuvenation)
- Future additional information will be detailed on **Application Notes** as a supplement to the **Clinical Work Book**

Indications for Use

Application	Treatment Variable	Fitzpatrick Skin Type					
		1	2	3	4	5	6
Hair Removal	Thin, Normal, Thick Hair	X	X	X	X	X	X
Photo Rejuvenation	Skin Rejuvenation (Pigmentation, Diffuse Redness and Skin Texture	X	X	X	X	%	%
Note: Patients with darker Fitzpatrick Skin Types (4 or above) or who are suntanned should always be treated with extra care and attention. **Key: X Allowed; % Not Allowed**							

⚠WARNING Ellipse Light has built in parameters to prevent treatment to patients whose skin type or level of pigmentation exceeds the maximum allowed. Never try to treat patients above these limits, treatment will be ineffective and will possibly result in a skin burn.

Note: Fitzpatrick Standard Skin Type Definitions

The table below gives a general description of the six skin types categorized by dermatologist Thomas B Fitzpatrick. Other combinations of hair, eye and skin colours can occur in each skin type.

⚠CAUTION Take care if treating dark skin with high-energy settings! Darker skin contains more (light-absorbing) melanin. Under treatment, absorption heats up the skin and gives a higher risk of epidermal burns. This should always be taken into account when treating sun-tanned patients or those with a Fitzpatrick skin type of 4 or higher.

Skin Type	Typical Skin Type Definition	Skin Reaction on overexposure to UV light	Comments on Skin Type
1	Red-blond hair Blue-green eyes Very light skin	Always burns Never tans	Often have freckles
2	Light to medium hair Light to medium eyes Light to medium skin	Usually burns Seldom tans	Should be the first consid eration in typing the aver age light skin (other than obvious skin type 1.The light burning or pinking exposure to sun will pigment to a “tan effect” by evening.
3	Medium hair Medium to dark eyes Medium to olive skin	Moderate burns Usually tans	Usually do not recognize that they burn moderately if exposure is moderate. Will comment that they “Can get a good tan with care”.
4	Dark hair Dark eyes Dark olive to light brown skin	Burns mildly Moderate browning	Usually consider they tan easily and with “moderate” exposure in northern climates, will not experience a burn very often. Will burn if visiting higher intensity locations.
5	Dark hair Dark eyes Brown skin	Seldom burns Dark brown	Seldom experiences a burn. Burning will usually occur after having no previous exposure for months, and then being exposed to very high intensity levels (100+ on the SUNSOR scale).
6	Dark hair Dark eyes Very dark skin	Does not burn Insensitive, does not burn	Individuals have very high pigmentation that affords exceptional protection in ultraviolet light.

1.3 Successful Treatments using Ellipse Light

General Treatments

General Pre-treatment care

Before treatment, always:

- Remove patient's make-up (to avoid skin burns).
- Ensure there are no tattoos or permanent make-up in the treatment area. These must not be treated as the pigment absorbs part of the light energy and this can lead to a skin burn.
- Shave the treatment area if required, and remove the shaved hairs from the skin.
- Apply optical coupling gel. See Section 5 Technical specifications
- Use eye protection (both operator and patient). See Section 4-2-1 Eye Protection

General Treatment Notes

Identify the skin type according to the Fitzpatrick skin type scale. Accurately enter this onto Ellipse Light, which will adjust the default energy setting according to the skin type and pigmentation selected.

Identify the degree of pigmentation (suntan). If necessary compare the treatment site pigmentation with an area not exposed to the sun.

Do not try to treat patients with a combination of skin type and pigmentation outside the indication of use. See Section 1-1Indications for Use.

Default settings are placed in the lower end of the therapeutic window. This is the area within a treatment where there is a notable beneficial effect with low risk of side effects. To optimize the results, the energy setting (J/cm²) can be increased to the upper part of the therapeutic window. This is found based on the user's clinical knowledge, by judging the skin reaction and the patient's tolerance of pain.

Use sufficient gel on the treatment area.

Place the Light Guide perpendicular to the skin surface to ensure maximum light penetration.

Always perform a test shot, based on the recommended settings. Observe both patient discomfort and skin reaction (erythema - redness). The test shot should be relevant to the treatment site, but should not be prominent.

Do not slide the applicator across the treatment site; lift it and place it down again. This avoids a build up of optical coupling gel on the side of the applicator, and reduces the risk of side effects.

If you need to shoot the same area again (maybe using a higher energy), allow the skin to cool for at least at least 1 minute between shots.

General Post-treatment Care

After the final shot remove the gel and dry the skin surface with a soft cloth. A cool pack placed against the skin may be comforting for the patient. Do not expose the treated area to sunlight or solaria for 1 month after treatment. Use a sun block - minimum SPF 60 (SPF 30 if hair removal) when exposure to sunlight is inevitable.

Hair Removal

Target Chromophore: Melanin

The target is melanin in the hair and hair bulb. These are heated to ensure conduction of heat to the hair follicle. Only hairs in the growing phase can be treated, therefore multiple treatments are necessary. Good results can always be achieved if treating dark hair on a fair skin. Treatment of blond, light-red or grey hairs is not effective because they have a lower melanin content.

Wavelength

The Ellipse HR applicator (REF 9APP7133) emits light with wavelength 600 nm - 950 nm. This gives high absorption in melanin. The penetration depth of these wavelengths is enough to reach even the deeper hair follicles.

Small areas of hair can be treated with the HR-S applicator (REF 99APP7116). This uses the same wavelengths as above but has a diameter of 8mm. Because of the size, the maximum possible energy is capped at 16.5J/cm2.

For dark skinned patients, the Ellipse HR-D Applicator (REF 9APP7114) emits light with wavelength 645 nm - 950 nm. This enables safe treatments in patients with a higher skin concentration of melanin. The penetration depth of these wavelengths is again enough to reach the deeper hair follicles.

Pulse Duration is dependant on hair thickness

The Ellipse Light system automatically selects the appropriate pulse duration, when the operator states the thickness of the hair. Thin hair needs less energy to heat up, and a relatively low level of energy is used. Thick hair needs more energy to heat up, and a higher energy level is used. In general the highest energy levels should only be used in connection with longer pulse durations.

Hair pre-treatment care

In the 30 days before treatment, do not:

- Pull out the hair with tweezers, wax or use depilatory creams, nor bleach the hair.
- Sunbathe or use solaria

Hair treatment

Mark the treatment borders with a RED pen. Do not use other colours, as they will absorb the light and cause skin burns.
Remember to shave the treatment area and remove all shaved hairs.
Press the applicator firmly against the skin surface. This increases the efficacy due to:

- Reduction of the distance between skin surface and hair.
- Squeezing blood out of the superficial blood vessels. This will reduce the absorption of light by the haemoglobins.

The energy can be increased until follicular or general erythema (redness) is observed or until the level of patient discomfort is reached.

⚠CAUTION **Note:** that in darker skin types (4 or 5) erythema may take from a few minutes to a few hours to develop. Therefore you should always make a test shot well in advance of starting treatment.

Synchronisation of the Hair Grow Cycle

The effect of a low energy setting can be to synchronise all hairs in the resting phases to an early anagen phase. This means more hairs are seen after the treatment, which might be a disappointment for a patient who is not informed of the possibility. The next treatment however, will be even more efficient, as more hairs are in the early growth phase.

Intervals between hair treatments:

The interval depends on the anatomic site treated as well as the individual patient. It is recommended to perform the next treatment when re-growth can be observed in the treated area.

Special for hair treatment:

The desired treatment effect is slight redness or swelling centred around the hair, although this is not always seen. Note that treatment of a skin type 6 patient (or a skin type 5 with light pigmentation) requires the HRD Applicator.

Skin Rejuvenation Procedure

Target Chromophores - Haemoglobin and Melanin

Melanin is produced in epidermal cells called melanocytes, and transported to structures called keratinocytes. Keratinocytes are destroyed if heated to 70°C for more than 1 ms.

Haemoglobin and oxyhaemoglobin are found in the blood inside the vessel. The light absorbed by the blood is transformed into heat, then conducted to the vessel wall. The protein in the vessel wall will be destroyed if it reaches 70°C for more than 1 ms. As a result the blood will coagulate and the destroyed vessel wall will gradually disappear, removing the unwanted small visible vessels and diffuse redness.

Wavelength

Skin Rejuvenation requires the VL-2 Applicator (REF 9APP7134). This emits light in the range of 555 nm - 950 nm with high absorption in the chromophores melanin and haemoglobin and no absorption by the competing chromophore water.

Pulse Duration

Diffuse redness and pigment is treated using a double 2.5 ms pulse, with a delay of 10ms to treat the entire area.

Energy settings

Treatment of diffuse redness and pigment is carried out with very short pulse duration and 7-9 J/cm^2.

Skin Rejuvenation pre-treatment care

Patients with skin types 1 2 or 3 are good candidates for Skin Rejuvenation procedure. Best results are obtained if the patient has a low degree of pigmentation from sun tanning or solarium

⚠CAUTION **Note:** Skin type 4 (or suntanned Skin Type 3) should be treated with caution. Skin Types 5 and 6 should not be treated.

Special for Skin Rejuvenation treatment

⚠CAUTION Closely examine thae pigmented lesions and vessels ensuring that all are benign. If in doubt, the patient should be referred to a spcialist for further examination including the possibility of a biopsy.

Skin Rejuvenation Post-treatment Care

Patient should expect 1-2 treatment sessions before clearance of all lesions. The final result and the number of treatments depend on a number of factors e.g., pigmentation, position (dermal or epidermal) and colour of the lesion, previous treatments, pre-treatment care.

Contraindications

It is not possible for this document to give a future-proof set of contraindications. The rate of production of new drugs (medications) means that new information on drugs (and combinations of drugs) appears daily. Most countries have an up to date register of drugs and their side effects, including photosensitivity. If in doubt, the user should seek expert medical opinion from those with the ability to research the effects of disease and genetic conditions, and further to research the side effects of medication. Such information can also be obtained by emailing clinical@3d.dk. Currently known contraindications are:

- Patients with any disease or genetic condition causing photosensitivity.
- Patients undergoing treatment with anticoagulants (anti-clotting drugs) or any medication causing sensitivity to light.
- Patients suffering from long term diabetes or haemophilia.
- Patients tending to produce keloids (raised red scars) or hypertrophic (abnormal amounts of) scarring.
- Patients with sun-tanned skin or fever.
- Patients taking topical or systemic steroids, or taking non-steroidal anti inflammatory drugs, as these actively work against the treatment.
- Patients who have smoked tobacco within 4 hours prior to treatment where the target chromophore is haemoglobin.

Contraindication Notes

Although not specifically contraindicated, patients who are pregnant or who have a heart pacemaker fitted are normally not treated. Hair treatment of pregnant patients is best deferred until 2-3 months after birth, as growth of body hair is synchronized at this time.

Chapter 2: TREATMENT SCENARIOS

⚠WARNING Before starting treatment, it is important that the operator has understood the technical aspects of using the equipment (see Sections 3 and 4). In addition, safe and efficient patient treatment requires suitable training in and basic understanding of, dermatologic evaluations and interaction between high-energy light and human tissue.

2.1 General

This chapter provides step-by-step instructions for removal of hair and for Skin Rejuvenation. Remember that buttons are pressed, by touching the screen where the button is located.

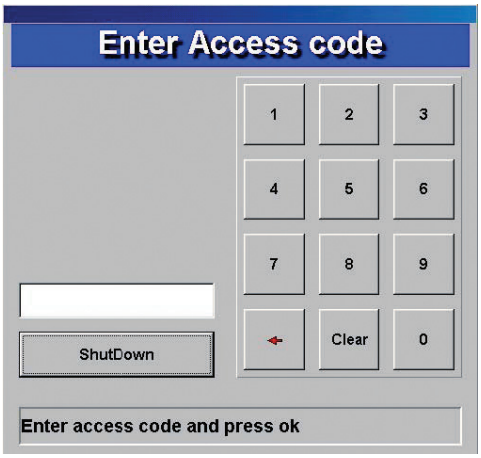
You can get relevant on-screen help by touching the selected settings near the buttons. Note that most of these are displayed as **blue boxes** but if the Current Energy setting chosen is not the same value as the system default it will be a grey (not a blue) box. You can also get help by pressing <MENU> and then <HELP>.

2.2 Logging On

The Ellipse Light is powered up using the switch at the rear of the cabinet. Press the "on" switch (symbol I) to power up and the "off" switch (symbol O) to turn off the power supply. (Refer to section 2-7 Shutdown).

An applicator needs to be connected to the Ellipse Light on power-up. The system will initially carry out a "self-test" to confirm the applicator is in place and that the system is working correctly. If the test reveals any irregularity, it will advise the appropriate action to take. You will not be able to treat a patient until the self-test is passed.

If you need to change applicators, follow the procedure shown in Section 3-1 Changing Applicators.



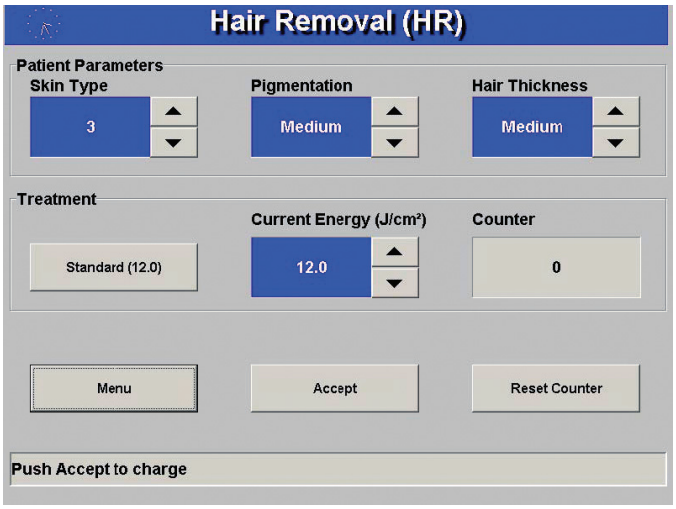
After the self-test has completed, you must enter the four-digit access code by clicking the 0-9 buttons. The default access code is 1234. This can be changed (see Section 2-8-4 Change Code). When a four digit access code has been entered, the Shutdown button will change to read OK. The operator can then enter the system by pressing <OK>.

If you want to clear the access code you have entered, press <Clear>, or press < ← > to clear the last digit entered.
If you press <Shutdown> button, the system will shut down.
When the access code has been accepted, you will be allowed access to one of the treatment screens.

2.3 Choice of Treatment Screens

Users are offered a choice of treatment screens dependent on the Applications used, Hair Removal (HR applicator REF 9APP7133), Hair Removal S (Small areas using HR-S Applicator REF 9APP7116) Hair Removal D (for Dark Skin using HR-D Applicator REF 9APP7114) and Skin Rejuvenation (VL-2 Applicator REF 9APP7134). Ellipse Light chooses the correct treatment screen based on the applicator (Hand Piece) used. Note that if you change applicators when Ellipse Light is shut down, the system will detect the change when you start the System again, and ask you to confirm the treatment you wish to perform. (See Section 3.1 Changing Applicators).

2.4 Treatment of a Patient (Hair Treatment



To treat a patient, follow the below given step by step guide. (Remember to check that the correct applicator (hand-piece) is connected before starting treatment).
Follow the Pre-Treatment procedure listed in the Clinical Work Book. This is also available as on-screen help by pressing <Menu> then <Help> and <Tips & Tricks>.

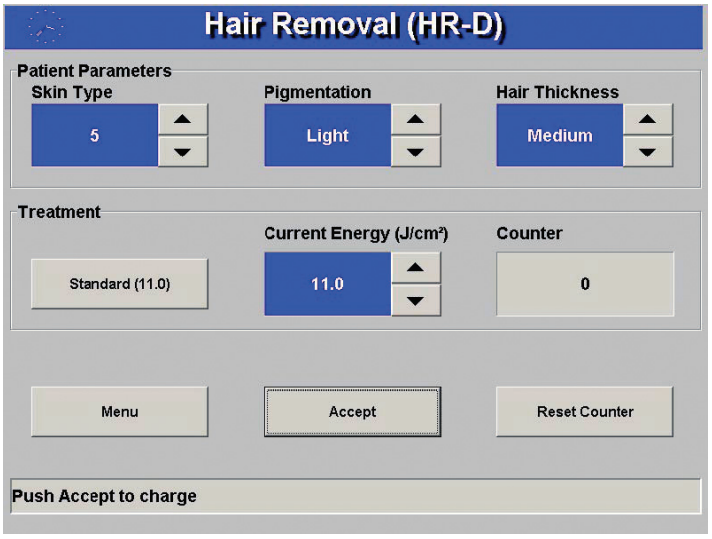
To keep track on the number of shots for this specific treatment, press Reset Counter before starting the treatment.

Enter the correct skin type of the patient to be treated by clicking the up/down buttons (▼ or ▲).

Enter the correct degree of skin pigmentation of the area to be treated by clicking the up/down buttons (▼ or ▲).

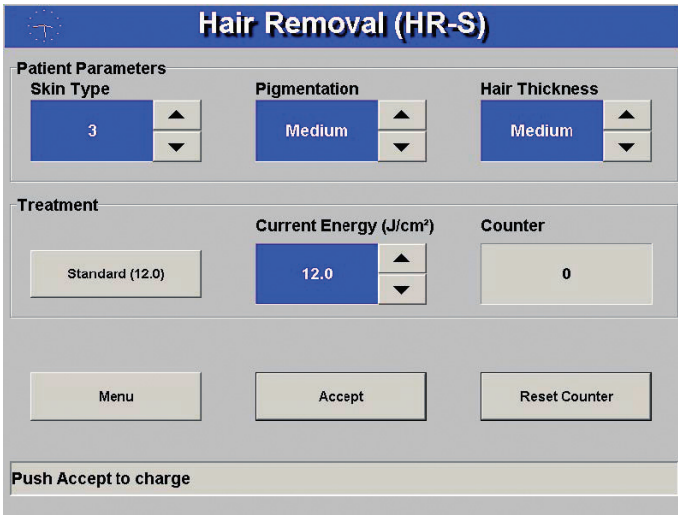
Enter the correct thickness of the hairs to be treated by clicking the up/down buttons (▼ or ▲).

The default Current Energy setting is automatically calculated. This is based on the skin type, pigmentation and hair type you have selectet.



Use of the various applicators is identical. They are chosen according to the patient Skin Type and Pigmentation combination.

Note that the default energies and maximum energies vary according to the applicator in use.



If you are treating a small area of hair (in the nose, ears, or between eyebrows) use of the HR-S Applicator is recommended.

FOR ALL HAIR TREATMENT

You must check that the Energy setting is safe and appropriate. Validate the data you have entered and press <Accept>.
Start treatment when the system displays Ready in the status field at the bottom of the screen. Use a test shot in an area relevant to the treatment area, but not too prominent.

Judge both the skin reaction, and the patient's response (discomfort level). The time that should be allowed for skin reaction depends on the Skin Type of the patient. Types 1 - 3 will usually react within a couple of minutes but for darker clients (skin type 4 - 5) it is advisable to wait at least 15 minutes before proceeding with the actual treatment Based on the reaction and response, it must now be decided if the suggested setting is safe and appropriate. If you have to adjust the Current Energy, this is done by clicking the up/down buttons (▼ or ▲) and pressing <Accept>.

When the treatment is done, terminate the treatment by pressing <Done>.

Remember: you can get on-screen help by pressing the setting (Skin Type, Pigmentation, Hair Thickness, Current Energy) concerned. If you change the Current Energy setting from the default, the blue field turns to grey. If you want to re-select the Standard Current Energy, then press <Standard>.

Note: for hair treatment, the default Current Energy is quite conservative (mild) and better results may be achieved by increasing the Energy slightly. This is because quite a wide "Therapeutic Window" exists. Only adjust the settings after a test shot has been taken. Any adjustment should be governed by the skin reaction and patient response.

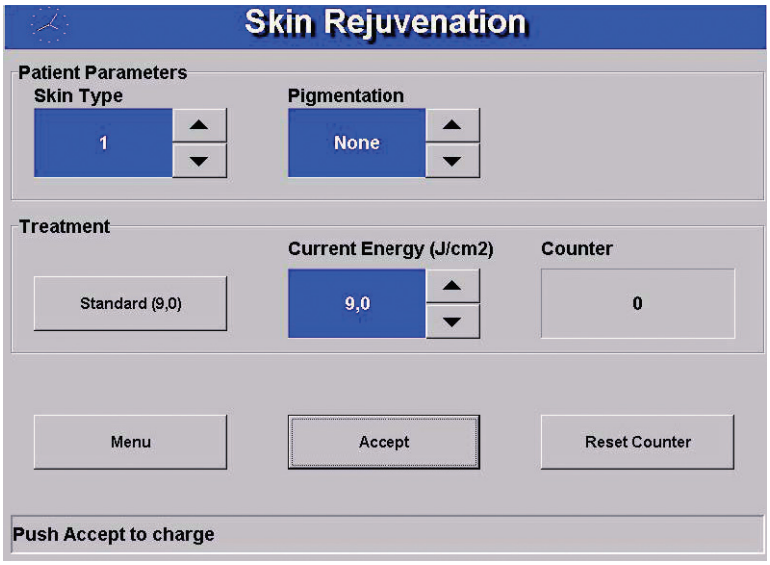
2.5 Treatment of a Patient (Skin Rejuvenation)

To treat a patient follow the below given step by step guide. (Remember to check that the VL-2 applicator (REF 9APP7134) is connected before starting treatment).

Follow the Pre-Treatment procedure listed in the Clinical Work Book, This is also available as on-screen help by pressing the top blue bar next to the clock. To keep track on the number of shots for this specific treatment, press <Reset Counter> before starting the treatment.

Enter the correct Skin Type of the patient to be treated by clicking the up/down buttons.(▼ or ▲).

Enter the correct degree of skin Pigmentation of the area to be treated by clicking the up/down buttons. (▼ or ▲).
The default Current Energy setting is automatically calculated. This is based on the skin type and, pigmentation you have selected.



You must check that the Energy setting is safe and appropriate. Validate the data you have entered and press <Accept>.

Start treatment when the system displays "Ready "in the status field at the bottom of the screen. Use a test shot in an area relevant to the treatment area, but not too prominent.

Judge both the patient's immediate response (discomfort level) and the skin reaction after 2 minutes.

The correct skin reaction is that the pigmented spots should darken. If the skin turns a greyish colour, the energy setting is too high and will result in a skin burn after 1 - 5 hours. Based on the reaction and response, it must now be decided if the suggested setting is safe and appropriate. If you have to adjust the Current Energy, this is done by clicking the up/down buttons (▼ or ▲) and pressing <Accept>.

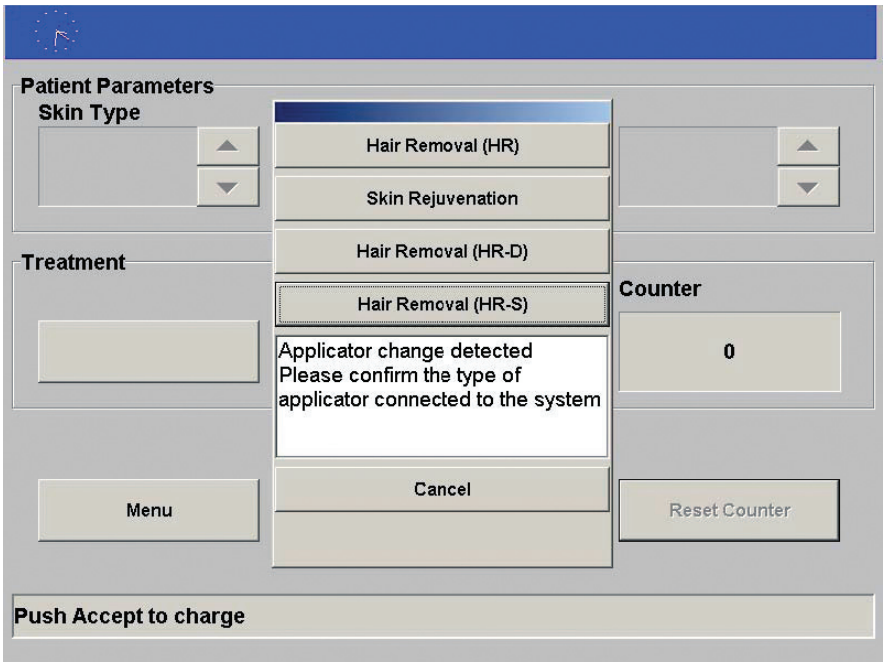
When the treatment is done, terminate the treatment by pressing <Done>. Remember: you can get on-screen help by pressing the setting (Skin Type, Pigmentation, Current Energy) concerned. If you change the Current Energy setting from the default, the blue field turns to grey. If you want to re-select the Standard Current Energy, then press <Standard>.

Note: for Skin Rejuvenation, the default Current Energy is very close to the optimum Energy .This is because the "Therapeutic Window" is very narrow. Only adjust the settings after a test shot has been taken. Any adjustment should be governed by the skin reaction and patient response, and if it is necessary to increase the Energy, only increase it by the minimum. Then take a new test shot (and observe the patient's immediate response and the skin reaction after 2 minutes again).

2.6 Changing an Applicator before or during treatment

It may be necessary to switch applicators before or during treatment (for example if treating a small area with the HR-S Applicator). The mechanism of the change is discussed in Section 3-1.

When the new applicator is physically connected, you will see a message asking you to confirm the change. Simply press the screen to confirm the applicator you have selected.



Menu Items (Overview)

To access menu items, press the button marked <Menu> that is found in the bottom left corner of the treatment screen. You will see the following image:

Software version

This is not important for normal day to day treatments, but will be needed if you have to speak to DDD or our distributor on service or related issues.

System

Pressing <System> will take you to the System Menu which deals with

- Service
- Self-Test
- System Language
- Changing the Access Code
- Changing (Replacing) the Applicator
- Updating the Software

These items are dealt with in Section 2.8 System Menu

Help

Press <Help> to provide you with a choice of all the help files that are available for Ellipse Light.

Cancel

Press <Cancel> to return to the previous treatment screen.

2.7 Shutdown

To close down the system, select <Menu> and then press <Shutdown>. Select <OK> to confirm this.

This will terminate the program and close down the operating system. After a short delay you will see a screen that says "it is now safe to turn off your computer". When you see this screen turn off power to the Ellipse Light by pressing the symbol **O** at the rear of the cabinet.

2.8 System Menu

System Menu items are accessed by pressing Menu and System and then selecting the appropriate item. The items are explained below.

Number of Applicator Shots

This shows the total number of shots that have been performed with the applicator type.

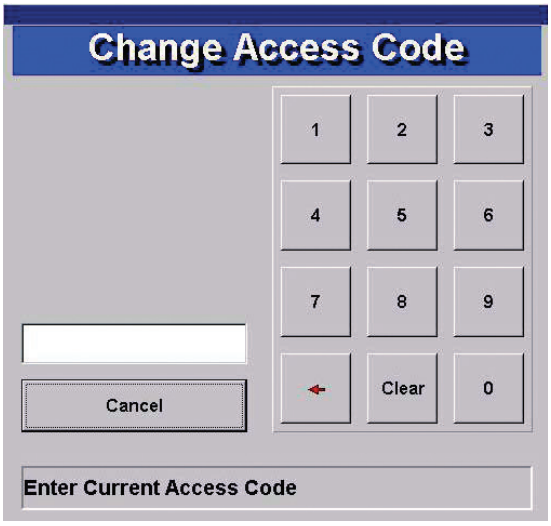
Service

The Service Menu requires a special access code. It is used only when installing or servicing the Ellipse Light.

Language

This is normally set up at the time of installation. However, pressing <Language> allows you to change the language used by Ellipse Light.

Change Code



Ellipse Light is supplied with a default access code "1234". This can be changed by selecting <Change Code>.

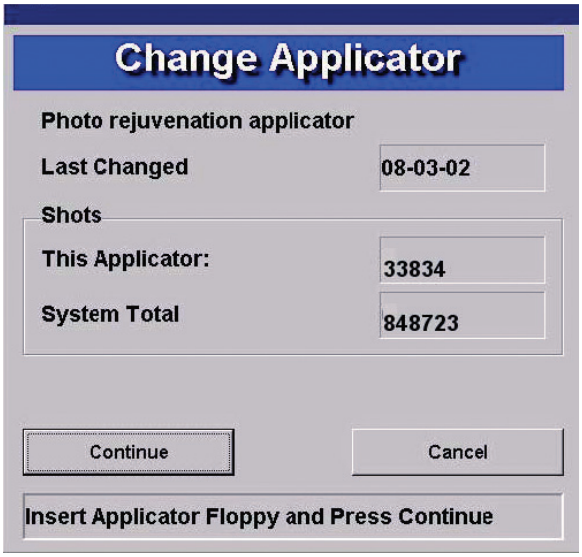
You first need to enter the current access code by pressing the screen over the numbers.

When you have entered four numbers, the status line at the bottom of the screen will ask you to enter the new code. Again, you need to enter 4 digits. Finally you will be asked to repeat the new access code as confirmation. Enter the 4 digits again and press <OK> to confirm the change.

You can cancel the operation, by pressing <Cancel> at any time before finally pressing <OK>.

Always ensure that you have written down any revised Access Code.

Change Applicator



Important Note: The System Menu item <Change Applicator> is used to notify the system that you are changing a damaged applicator (hand-piece) with a new one. It is not used for switching between Hair and Skin Rejuvenation applicators when performing different treatments.

More information, including how to switch between Hair and Skin Rejuvenation Applicators is given in Section 3-1 Changing Applicators.

Update Software

As new treatments develop, these can be introduced by choosing the System Menu item <Update Software>. Select <Update Software>, insert the disk(s) containing the update and follow the on-screen instructions.
Press <Cancel> to return to the previous treatment screen.

Chapter 3: MAINTENANCE

3.1 Changing Applicators

The procedure for changing the applicator is as follows:

Note: if you are changing the applicator for refurbishment or repair, you should follow steps 1 -5. If you are simply changing from hair to skin rejuvenation or skin rejuvenation to hair you should follow steps 3-5 only.

⚠WARNING To prevent the risks of light discharge, ensure that any treatment is concluded by Pressing <Done> on the treatment screen, before changing the applicator.

1. (For Refurbishment/Repair Only.) Press <Menu>, then <System>, then Change Applicator>
2. (For Refurbishment/Repair Only.) Insert the floppy disk into the drive, and choose < Continue> Data will be written onto the floppy disk. Press <Close>, when prompted to do so on screen. Remove the disk. Write the Serial Number of the "old" Applicator on the floppy disk and pack both together for shipping*.
3. Physically release the cable relief at the back of the cabinet. Unplug the electrical connector and the two cooling water fittings. A few drops of cooling water may leak from the fittings before the shut valve activates.
4. Remove the "old" applicator and introduce the "new" by reconnecting the two cooling water fittings and the electrical connector. Reposition the cable relief. Make sure the water tubes are not "kinked". It might be necessary to turn the cable relief.

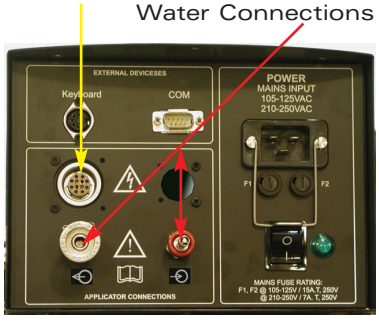
⚠CAUTION Always reposition the cable relief after replacing the applicator in order to avoid damage to the applicator cable and connectors.

*Note that you should follow the agreed return procedure if shipping an applicator for refurbishment/repair.

Release the cable relief

Electrical Connection

Water Connections



Reposition the cable relief

3.2 Filling and Draining the Water Supply

⚠CAUTION Only distilled or demineralised water should be used to fill Ellipse Light. Ensure that no applicator is connected to the System, and that you have selected <Menu> and <System>.

Filling the System

Attach the water tubing to the applicator cooling water input. This is labeled. Place an excess water cup under the cabinet to collect excess water (Fig 2). Lift the funnel and pour water into it (Fig 3) until excess water begins to run into the drip tray.

When 1 dl (100cc) water has flowed out, carefully remove the tubing from the applicator cooling water input and discard the excess in the cup.
Do not run the Self Test on a drained system.

Note also that it is not necessary to have the Ellipse Light switched on when adding water.

Draining the System

⚠CAUTION Ensure that no applicator is connected to the System, and that you have selected <Menu> and <System>.

Place an empty 2 litre container, on the floor near the system to collect excess water. Attach one end of the water tubing to the applicator cooling water outlet. This is labeled ⟳

Hold the other end of the tube in the container.

Press <Self Test>. The pump operates when the Self-Test is running.

It may be necessary to repeat the Self Test if you start with a completely full system. The end point is when water ceases to flow out.

When draining the system, it is likely that the Self Test will result in an error message being displayed. In this occasion the message can be ignored.

When water ceases to flow out, remove the tubing from the applicator cooling water output and discard the excess in the container. Because of the risk of impurities in the container, the water must not be re-used.

3.3 System Disinfection

Applicator Disinfection

It is essential that any areas that come into direct contact with the patient should be regularly inspected, cleaned and disinfected.

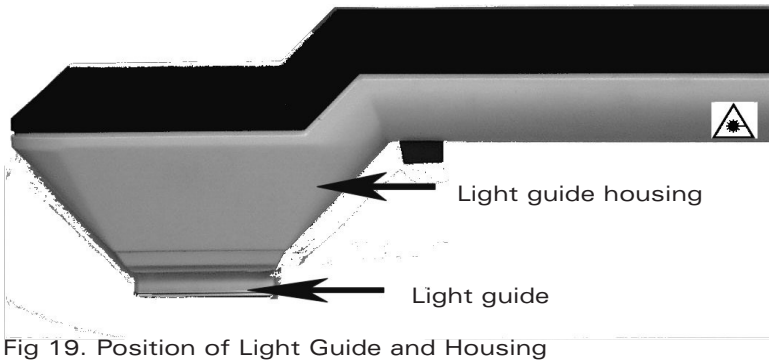


Fig 19. Position of Light Guide and Housing

This applies particularly to the light guide and the applicator. Between patients, the light guide and the light guide housing should be wiped with a mild soap solvent, followed by disinfection using a non-flammable disinfectant (for example peracetic acid) that is capable of killing bacteria, fungal spores and viruses. At least daily, visually inspect the applicator for any signs of damage. Once a week all applicator surfaces should be disinfected.

Cabinet Cleaning

Cleanliness is a prime rule in maintaining equipment. At least once a month external metallic surfaces should be wiped to remove any foreign material that may have accumulated.
Painted and plastic surfaces should be cleaned using a clean cloth moistened with a solution of soap and water. Clean the display using a clean cloth dampened with a mild window cleaning solution. Ensure that the cloth is not too wet, as no excess moisture should be allowed to run into the cabinet.

3.4 Technical Requirements

Maintenance

DDD or a DDD representative should perform all system maintenance. The following maintenance intervals are recommended:

- Every 6 months if powered more than 20 hours per week.
- Every 12 months if powered less than 20 hours per week.

Local conditions and dusty environment may shorten the intervals.
Applicator lifetime may be reduced by lack of maintenance, or lack or water.

Temperature

If the temperature in a clinic using Ellipse Light drops below freezing point, damage can be caused to the cooling system. To prevent this, keep Ellipse Light in a room above 5^0 Celsius or drain the cooling system of fluid. (See Section 3.2) Note the working temperature should be 15 - 30^0 C.

Storage Cabinet and Applicator

If the Ellipse Light need to be stored, a number of precautions need to be taken in order not to damage the equipment. For long time storing (more than 6 month) the shipping box can be used if it is available (if not consult your DDD representative). The shipping box can be stored standing or lying on the pallet.

Storing Precautions:

- The storage temperature must be within 5-40^0 Celsius, 20 - 80%, non condensing
- Protect the cabinet using a plastic cover
- Remove the applicator from the cabinet and store it separately
- For long time storing the shipping box can be used (consult your DDD representative).
- For long time storing (or if the temperature will drop below 5^0 Celsius), the cooling system must be drained of fluid (See Section 3.2).

Chapter 4: SAFETY

4.1 Introduction

This chapter contains important information concerning potential hazards and general safety precautions. The purpose of the safety instructions is to draw attention to potential hazards if instructions are ignored. These hazards may lead to accidents or serious injury to the patient, operator or service personnel.

Ellipse Light incorporates many safety features to protect the patient and the operator. However, as with all medical devices, safe use of Ellipse Light relies on a "safe attitude" from a suitably trained Operator. Do not use the system if a malfunction of the equipment or a safety problem is believed to exist.

Restrictions On Use

⚠CAUTION This equipment is intended to be use by qualified personnel only and only after they have been trained to use the equipment. Do NOT attempt to run or install any software - other than that provided by DDD - on the built in computer system.

⚠WARNING Using controls or adjustments or performing procedures other than those specified in this manual may result in severe personal injury or equipment damage.

⚠WARNING Injury to patient due to unintended flash release. Do not leave the equipment in a condition ready to flash at any time.

Hazards

⚠CAUTION Certain hazards are associated with the application of intense light energy to the skin. For this reason it is important that Ellipse Light is used only by suitably trained personnel, who understand both the clinical applications and the dynamics of light-tissue interaction.

Proper evaluation of both patient skin type and pigmentation is of paramount importance for efficient operation; it is therefore vital that a thorough dermatological examination is carried out prior to any treatment. Dark skin, whether natural or due to sun-tan, will increase the risk of side effects such as burns, and will also reduce the efficiency of the treatment. Be aware that pigmentation may vary over the treatment area and that absorption will be affected by pigmented nevi or tattoos.

Eye Protection

⚠WARNING Ellipse Light emits high energy, broad-spectrum light flashes that could cause severe eye damage. During treatment, the patient and operator must wear protective eyewear of the type recommended below:

	Eyewear Type	Cutoff Wavelength	Marked (colour)	DDD REF No.
Patient	Goggles	Provides complete optical protection		2EYE0801
Operator	Eye Protection Hair Removal	615-720 nm OD factor > 3 600-615nm OD-faktor > 2	Green	2EYE0800
	Eye Protection Skin Rejuvenation	530-710 nm OD1.5	Blue	2EYE7002

⚠CAUTION Never trigger the flash lamp without warning all personnel present.

⚠CAUTION Never leave a patient unattended if the system is in the ready mode.

⚠WARNING Never direct the Light Guide towards the eye. Aim away from the eye and treat the cheek bone as the highest point that can be treated. If necessary, move skin to be treated down over the cheek bone or up over the frontal cranial bone to use the bone as an additional shield.

Other Patient-Related Hazards

Injury to the patient's eyes and skin may result from incorrect use of the equipment. Always take the following precautions:

⚠WARNING Always follow the Patient Parameters Set-up instruction detailed in this manual.

⚠CAUTION No part of the area to be treated should be covered with any type of metal foil. When exposed to light radiation, foil may heat up and cause epidermal damage.

⚠WARNING Never use flammable liquids to clean the skin or prepare it for treatment. Use soap and water for skin cleaning, wash the skin afterwards with pure water and dry it before applying the coupling gel. Ensure that no shaved hair is present on the skin or on the applicator.

⚠WARNING Abnormalities of the skin, such as pigmented lesions, birth marks and tattoos must be evaluated by a medical doctor or dermatologist with experience in photo-therapeutics prior to treatment.

⚠WARNING The default settings are suggestions only. The operator is responsible for patient safety and should only press the Accept button once satisfied that the settings are appropriate. No default settings should be accepted unless a thorough dermatological evaluation has been carried out.

⚠CAUTION Dark skinned patients should only be treated with extreme caution. Take a sample shot and evaluate reactions to this before continuing.

⚠WARNING When doing hair removal over tattooed regions (including permanent make-up) the tattoo may be partly removed or discoloured, or epidermal adverse effects may be noted.

Operator Related Hazards

Severe injury to the operator could be caused by incorrect use of the equipment. Please ensure that the following precautions are observed:

⚠WARNING Do not use a power cable other than that supplied with the system. The system must be connected to a 3-pin power point (i.e. a socket with protective earth). Contact a local electrician as necessary.

⚠WARNING Only power the Ellipse Light system as specified on the rear of the cabinet. If the voltage specified does not correspond with that of the local supply, please contact your DDD representative who will be able to rectify the problem.

⚠WARNING Never use the Ellipse Light System if the System is wet or appears to be leaking water.

⚠CAUTION Do not place coffee cups or other liquid containers on the Ellipse Light. Spillage may damage the system and lead to malfunction.

⚠WARNING Ellipse Light has covers to protect operators from electrical shock and mechanical hazards. Always contact qualified service personnel for your servicing needs. Do not attempt to service the equipment yourself and do not remove any covers.

⚠CAUTION Do not lean anything against the equipment. Doing so could cause equipment damage.

Fire Hazards

Ellipse Light emits high energy light flashes that, when absorbed in any material can cause a dramatic increase of temperature or even cause the material to catch fire. To prevent this take the following precautions:

⚠WARNING Never expose flammable material to the radiation emitted from the Ellipse Light.

⚠WARNING Cleaning: Never use flammable liquid like alcohol to clean or disinfect any part of Ellipse Light. DDD recommends cleaning the applicator with a mild soap solvent, followed by disinfection using a mild non-flammable disinfectant. (see Section 3-3 System Disinfection).

⚠WARNING Equipment not suitable for use in the presence of flammable mixtures.

General Precautions

⚠CAUTION Do not attempt to operate the Ellipse Light System without the applicator connected.

⚠CAUTION Air bubbles trapped in the applicator must be removed before releasing the first shot - if not the applicator may stop working after a few shots.

⚠CAUTION Always reposition the applicator in the holder on the front of the cabinet when not in use.

⚠WARNING Always press <Done> before replacing the applicator.

⚠WARNING Do not attempt to use the Ellipse Light System if a safety problem is known to exist.

⚠WARNING Do not attempt to use the Ellipse Light System if an applicator is leaking cooling water.

⚠WARNING All areas that come into direct contact with the patients should be regularly cleaned and disinfected. This applies particularly to the light guide and the applicator (see Section 3-3 System Disinfection).

⚠WARNING Improper cleaning may result in equipment damage. This applies particularly to the light guide (see Section 3-3 System Disinfection).

4.3 System Safety Labeling

Warning against Powerful Loght radiation from the applicator. Avoid directly eye exposure. See accompanying documents.

Warning that a DANGEROUS VOLTAGE may be present

Applicator connection point

Applicator cooling water output

Applicator cooling water input

4.4 CE Conformity

CE 0543

Ellipse Light conforms with the requirements of council directive 93/42/EEC concerning medical devices, and therefore bears the CE mark of Conformity:

Safety Classification: The Ellipse Light has the following classifications:

Class IIb according to Directive 93/42/EEC concerning medical devices.

Class I, Type B according to EN 60601-1 safety standard.
This equipment requires a reliable protective earth connection.

4.5 IEC Symbols Used

Denotes Protective Earth Point

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Alternating Current

I

ON/Power

O

Off/Power

This symbol signifies:

105-125 VAC &
210-250 VAC
50 / 60 Hz
1.3 KVA

Input Voltages
Input Frequency
Input Power

Type B Equipment

Manufacturer

Attention: Consult accompanying documents for detailed instructions before proceeding.

Chapter 5: TECHNICAL SPECIFICATIONS

GENERAL SPECIFICATIONS

Dimensions (d x w x h)	700 mm x 518 mm x 1110 mm
Weight	107 kg
Noise Max	55 dBA
Electrical input	105 - 125 10% / VAC - 15 A
	210 - 250 10% / VAC - 7.5 A
Working Temperature	15 - 30º C
Relative Humidity	10 - 75 %

OUTPUT

Light Source	Intense Pulsed Light (I^2PL)
- Pulse Duration: Thin Hair	15 ms.
- Pulse Duration: Medium Hair	20 ms.
- Pulse Duration: Thick Hair	40 ms.
- Pulse Duration: Skin Rejuvenation	2 x 2.5 ms delay 10 ms.
- Charge Time (Min - Max)	1.5 - 3.8 sec.

ACCESSORIES

Optical Coupling Gel - REF 2GEL0826 (250g) or 2GEL1342 (5kg)

APPLICATORS

Weight excl. Cable	500 g
Hair Applicator (HR)	REF 9APP7133
- Wavelength	600 - 950 nm
- Output (Max)	21 J/cm2
- Foot Print (Spot Size)	10 mm x 48 mm
Dark Skin Hair Applicator (HR-D)	REF 9APP7114
- Wavelength	645 - 950 nm
- Output (Max)	18 J/cm2
- Foot Print (Spot Size)	10 mm x 48 mm
Hair Applicator-Small (HR-S)	REF 9APP7116
- Wavelength	600 - 950 nm
- Output (Max)	16.5 J/cm2
- Foot Print (Spot Size)	ø 8mm
Skin Rejuvenation Applicator(VL-2)	REF 9APP7134
- Wavelength	555 - 950 nm
- Output (Max)	12 J/cm2
- Foot Print (Spot Size)	10 mm x 48 mm

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CE 0543

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